

1415



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,555	01/19/2001	Carlos F. Barbas III	278012001420	1190
25225	7590	03/09/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,555

Applicant(s)

BARBAS ET AL.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/12/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 28, 31, 50, 54, 55, 56, 97 and 133-137 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**Continuation Sheet (PTOL-326)**

**Application No. 09/765,555**

Continuation of Disposition of Claims: Claims pending in the application are 1,3-8,11,13-16,18-22,28-31,36-44,46,48-66,68-74,76-85,88,91-95,97-100 and 133-137.

Continuation of Disposition of Claims: Claims allowed are 1,3-8,11,13-16,18-27,29,30,36-44,46,48,49,51-53,55,57-66,68-74,76-85,88,91-95 and 98-100.

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/25/03 and the supplemental response filed 12/12/03 in reply to the Office action of 05/21/03 have been entered. Claims 17, 23-27, 47, 73, 75, 89 and 138 have been cancelled. Therefore, claims 1, 3-8, 11, 13-16, 18-22, 28-31, 36-44, 46, 48-66, 68-74, 76-85, 88, 91-95, 97-100, and 133-137 are pending and are under consideration.

All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment to the claims.

#### ***Claim Objections***

At claim 4, "plant cell" in line 14 should be replaced with ----plant---, for clarification.

#### ***Claim Rejections - 35 USC § 112***

Claims 28, 50, 54, 56, 97 and 133-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 05/21/03. Applicant's arguments filed 09/25/03 have been fully considered but are not found persuasive.

Claim 28 is indefinite for depending upon cancelled claim 23. The metes and bounds of "metabolic pathway enhances an input or output trait in a plant cell" is unclear, and the specification fails to define what is encompassed by the phrase. The

claim is open to a variety of interpretations. Applicant argues that the terms "input trait" and "output trait" are art-recognized terms, and Applicant provides biotechnology dictionary for the definitions of these terms. This is not persuasive because the terms "input trait" and "output trait" are so broad that one skilled in the art cannot determine the metes and bounds of the claimed invention. Canceling the claim can obviate the rejection.

At claim 50, "plant cells" lack antecedent basis in claim 1. Replacing "plant cells" with ---plant cell--- can obviate this rejection

Claim 54 does not further limit claim 52.

At claim 56, "plant cells" lack antecedent basis in claim 4. Replacing "plant cells" with ---plant cell--- can obviate this rejection.

At claim 94, "genetically modified plant cell" lacks antecedent basis.

Claim 97 is indefinite for depending upon cancelled claim 89. Also, "genetically modified plant cell" lacks antecedent basis.

At claims 133-134, and 136-137, "derived" renders the claims indefinite because it is unclear what is being retained in the derived product. Applicant argues that one of ordinary skill in the art would understand that the derived product contains a framework from the ZFPs specified in the claims. This is not persuasive because the word "derived" implies that the derived product contains derivatives other than a framework from plant ZFPs. It is suggested that "derived" be replaced with ---obtained---.

***Claim Rejections - 35 USC § 112***

Claims 28 and 55 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of modulating the expression level of a target gene in a plant/plant cell by transforming the plant cell/plant with nucleotide sequences encoding zinc finger proteins including ZFPm1 (SEQ ID NO: 38), ZFPm2 (SEQ ID NO: 39), ZFPm3 (SEQ ID NO: 40), ZFPm4 (SEQ ID NO: 41), and the ZFPAP3 (SEQ ID NO: 43), an expression vector comprising said nucleotide sequences, transformed plant, plant cells, and seed comprising said expression vector, does not reasonably provide enablement for a method to stably modulate the expression level of any target gene with a nucleotide sequence encoding a synthetic zinc finger protein in a plant cell/plant, wherein the target gene encodes a protein that controls a metabolic pathway that enhances an input or output trait in the plant cell/plant, or wherein the modulation changes the phenotype of the plant cell. This rejection is repeated for the reasons of record as set forth in the last Office action of 05/21/03. Applicant's arguments filed 09/25/03 have been fully considered but are not found persuasive.

Applicant argues that the claimed methods to stably modulate the expression level of any target gene in a plant/plant cell by transforming the plant/plant cell with a nucleotide sequence encoding a synthetic zinc finger protein, wherein the target gene encodes a protein that controls a metabolic pathway that enhances an input or output trait in the plant cell/plant or modifies the phenotype of the plant cell/plant are reasonably enabled by the instant specification. Applicant relies the following points to support this position: 1) the specification provides guidance for the construction and use

of novel synthetic ZFPs which are representative sample of the claimed synthetic zinc finger proteins; use of linkers; ZPFs useful for framework regions; useful effector domains for fusion with ZFPs; methods for identifying potential ZFP binding sites and characterization of DNA binding specificity; methods for selecting target sequences; methods for identifying and isolating promoters for targeting by the ZFPs; plant transformation and regeneration methods; stable expression of ZFPAP3 and resulting phenotype.

These arguments are not persuasive because the arguments are not commensurate in scope with the rejected claims. Applicant's arguments are persuasive only with respect to the use of nucleic acids encoding synthetic zinc finger proteins having the defined characteristics to modulate expression level of a target gene in a plant/plant cell. Applicant has not provided guidance for a method to stably modulate the expression level of any target gene, wherein the modulation changes the phenotype of a plant/plant cell. Wherein the claims are directed to methods for modulating expression level of a target gene encoding a protein that changes the phenotype of a plant, the scope of enablement is limited to the use of target genes encoding AP3 and myoinositol 1-phosphate synthase (Mips) or phytic acid. Applicant has not provided sufficient guidance for a method wherein target genes other than the MIPS gene and the AP3 gene is regulated through the expression of a synthetic zinc finger protein for phenotypic changes. Applicant has not shown that any other genes could be stably modulated by this method for phenotypic changes. In addition, neither the prior art nor Applicant's specification provides evidence that shows any phenotype can be altered

with laboratory made zinc-finger protein technology, and/or if the phenotype altered will remain stable and will be inherited to subsequent generation without reversion.

With respect to claim 28, Applicant provides no guidance for a method to stably modulate the expression of a target gene encoding a protein that controls a metabolic pathway that enhances an input or output trait in the plant cell/plant. The method involves various products, genes, enzymes and method steps that are not enabled by the instant specification. The specification provides no more than an invitation to experiment requiring undue and excessive experimentations.

*In Genentech Inc v. Novo Nordisk A/S* (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention...".

Therefore, for the reasons above and in the last Office action, the claimed invention is not enabled throughout the broad scope.

Claim 31 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as



set forth in the last Office action of 05/21/03. Applicant's arguments filed 09/25/03 do not address this rejection, therefore the rejection is maintained.

Applicant has not provided guidance for a method for treating abnormal expression of a target gene in plant cells by using a zinc finger protein or any other compound. The prior art does amend the deficiency. One skilled in the art who is willing to practice the invention is left with undue trial and error experimentation because neither the instant specification nor the prior art provides any guidance for how to identify a disorder associated with upnormal gene expression in plant cells and/or how to treat said abnormality with zinc finger proteins. The rejection is maintained.

#### ***Written Description***

Claims 28, 30, 31, 55 and 70-71 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 05/21/03. Applicant's arguments filed 09/25/03 have been fully considered but are not found persuasive.

Applicant's argument that the claimed methods are sufficiently described is not persuasive because the instantly rejected claims are not limited to the modulation of gene expression using synthetic zinc finger proteins with defined characteristics but to undescribed methods that involve unknown metabolic pathways, genes, enzymes, products, which Applicant clearly was not in possession at the time of filing. Applicant

Art Unit: 1638

has not described a method to stably modulate the expression of a target gene encoding a protein that controls a metabolic pathway that enhances an input or output trait in the plant cell/plant, or wherein the modulated gene expression changes the phenotype of a plant/plant cell. Applicant has not described a method for treating abnormal expression of a target gene in plant cells by using a zinc finger protein or any other compound, nor Applicant describes how to identify a disorder associated with upnormal gene expression in plant cells and/or how to treat said abnormality with zinc finger proteins, as stated in the last Office action. Claims 30 and 70-71 are rejected because genes encoding a cofactor and a phytic acid are not described in the specification or in the prior art. Therefore, for the reasons discussed above and in the last Office action, the rejection is maintained.

### ***Remarks***

The claims are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method of stably modulating the expression of a target gene with a nucleic acids encoding synthetic zinc finger proteins having the identified characteristics, nor that the prior art teaches an expression vector, plant/plant cell/seed comprising said nucleic acids.

Claims 1, 3-8, 11, 13-16, 18-27, 29-22, 29-30, 36-44, 46, 48-49, 51-53, 55, 57-66, 68-74, 76-85, 88, 91-95, and 98-100 are allowable.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and After final

Application/Control Number: 09/765,555

Page 9

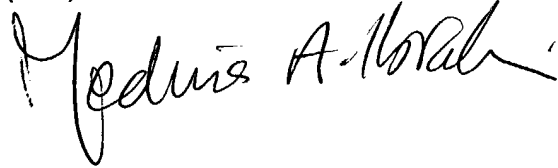
Art Unit: 1638

responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

3/3/04

Mai

A handwritten signature in black ink, appearing to read "Medina A. Mora". The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.